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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,773	11/14/2001	Kiamars Hajizadeh	3873 P 011	1833

7590 05/09/2005

Wallenstein & Wagner, Ltd.  
53rd Floor  
311 S. Wacker Drive  
Chicago, IL 60606-6622

EXAMINER

SWARTZ, RODNEY P

ART UNIT PAPER NUMBER

1645

DATE MAILED: 05/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/990,773

Applicant(s)

HAJIZADEH, KIAMARS

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22october 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-8,13-18,20-26 and 29-34 is/are rejected.
- 7) ☒ Claim(s) 3, 9-12,19,27-28 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 12/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

1. Applicant's Response to Office Action, received 22 October 2004, is acknowledged.

Claims 1, 14, 28, and 32 have been amended.

2. Claims 1-34 are pending and under consideration.

### **Rejections Withdrawn**

3. The rejection of claims 1-24 and 28 under 35 U.S.C. 112, second paragraph, as being indefinite for "a pair of antibodies specific to PrP<sup>Sc</sup>" is withdrawn in light of the amendment of the claims.

4. The rejection of claim 32 under 35 U.S.C. 112, second paragraph, insufficient antecedent basis for "labeled antibody" is withdrawn in light of the amendment of the claim.

5. The rejection of claims 25-27 and 29-32 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, is withdrawn.

### **Claim Rejections - 35 USC § 103**

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1, 2, 4-8, 13-18, 20-26, and 29-34, rejected under 35 U.S.C. 103(a) as being unpatentable over Oesch et al (*Arch. Virol.*, 16(suppl):189-195, 2000) in view of Sy et al (U.S. Pat. No. 6528269) and Grathwohl et al (*J. Virol. Meth.*, 64:205-216, 1997).

The claims are drawn to a method for detecting prion disease in animal carcasses using two different antibodies specific for PrP<sup>Sc</sup> and correlating the result to the carcass.

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Oesch et al teach the claimed method of screening for BSE in cattle regularly slaughtered at Swiss abattoirs in order to remove carcasses which test positive for prion by antibody assay. (Summary; **Materials and Methods** section).

However, Oesch et al teach the use of only one antibody specific for PrP<sup>Sc</sup> and do not teach all of the reagents in the dependent claims.

Sy et al teach multiple monoclonal antibodies specific for PrP<sup>Sc</sup> and immunoassays utilizing them (Abstract; col. 8, line 18 to col. 22, line 4).

Grathwohl et al also teach immunoassays using antibody specific for PrP<sup>Sc</sup> as well as the reagents. In addition, Grathwohl et al teach variations on immunoassays in order to optimize tissue handling and prion detection (Abstract; Figure 1; section 2.2; section 2.4; section 3.1-3.3).

Thus, it would have been obvious to one of ordinary skill in the art of animal meat production to utilize the procedures of Oesch et al during slaughter and to maximize the effectiveness of the procedures of Oesch et al by utilizing multiple antibodies, as taught by Sy et al, and maximum reagent conditions, as taught by Grathwohl et al, in order to facilitate recognition and removal of animal carcasses from production as quickly as possible.

### **Claim Objections**

8. Claims 3, 9-12, 19, 27, and 28 are objected to as being dependent from rejected claims. Appropriate correction is required.

### **Conclusion**

9. No claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571)

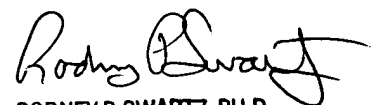
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272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



RODNEY P. SWARTZ, PH.D.  
PRIMARY EXAMINER  
Art Unit 1645

April 30, 2005